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William R. Schmidt, II
Wenderoth, Lind & Ponack, L.L.P.
1030 15th Street, N.W.
Suite 400 East
Washington, D.C. 20005

In Re: Patent Term Extension
Application for
U.S. Patent No. 6,114,319

Dear Mr. Schmidt:

A certificate under 35 U.S.C. § 156 is enclosed extending the term of U.S. Patent No. 6,114,319 for a period of 371 days. While a courtesy copy of this letter is being forwarded to the Food and Drug Administration (FDA), you should directly correspond with the FDA regarding any required changes to the patent expiration dates set forth in the Patent and Exclusivity Data Appendix of the Orange Book (Approved Drug Products with Therapeutic Equivalence Evaluations) or in the Patent Information set forth in the Green Book (FDA Approved Animal Drug Products). Effective August 18, 2003, patent submissions for publication in the Orange Book and Docket *95S-0117 need to be submitted on form FDA-3542 which may be downloaded from FDA's Electronic Forms Download Website:
<http://www.fda.gov/opacom/morechoices/fdaforms/default.html>
(<http://www.fda.gov/opacom/morechoices/fdaforms/FDA-3542.pdf>).

Inquiries regarding this communication should be directed to Raul Tamayo by telephone at (571) 272-7728, or by e-mail at raul.tamayo@uspto.gov.

Mary C. Till
Senior Legal Advisor
Office of Patent Legal Administration
Office of the Associate Commissioner
for Patent Examination Policy

cc: Office of Regulatory Policy
Food and Drug Administration
10903 New Hampshire Ave., Bldg. 51, Rm. 6222
Silver Spring, MD 20993-0002

RE: DUREZOL® (difluprednate
ophthalmic emulsion)
FDA Docket No.: FDA-2009-E-0021

Attention: Beverly Friedman

UNITED STATES PATENT AND TRADEMARK OFFICE

(12) CERTIFICATE EXTENDING PATENT TERM
UNDER 35 U.S.C. § 156

(68) PATENT NO. : 6,114,319
(45) ISSUED : September 5, 2000
(75) INVENTOR : Masako Kimura et al.
(73) PATENT OWNER : Senju Pharmaceutical Co., Ltd.; Mitsubishi
Chemical Corporation
(95) PRODUCT : DUREZOL® (difluprednate ophthalmic
emulsion)

This is to certify that an application under 35 U.S.C. § 156 has been filed in the United States Patent and Trademark Office, requesting extension of the term of U.S. Patent No. 6,114,319 based upon the regulatory review of the product DUREZOL® (difluprednate ophthalmic emulsion) by the Food and Drug Administration. Since it appears that the requirements of the law have been met, this certificate extends the term of the patent for the period of

(94) 371 days

from May 12, 2018, the original expiration date of the patent, subject to the payment of maintenance fees as provided by law, with all rights pertaining thereto as provided by 35 U.S.C. § 156(b).



I have caused the seal of the United States Patent and Trademark Office to be affixed this 30th day of June 2011.

David J. Kappos

David J. Kappos
Under Secretary of Commerce for Intellectual Property and
Director of the United States Patent and Trademark Office